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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/975,502

10/11/2001

Jerry G. Henslee

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7590

06/22/2006

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EXAMINER

HARRIS, ALANA M

ART UNIT

PAPER NUMBER

1643

DATE MAILED: 06/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/975,502

Applicant(s)

HENSLEE ET AL.

Examiner

Alana M. Harris, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 February 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 2-4 and 6-8 is/are pending in the application.
- 4a) Of the above claim(s) 6-8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-4 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Arguments***

1. Claims 2-4 and 6-8 are pending.  
Claims 6-8, drawn to non-elected inventions are withdrawn from examination.  
Claims 2-4 are examined on the merits.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Claim Rejections - 35 USC § 103***

3. The rejection of claims 2-4 under 35 U.S.C. 103(a) as being unpatentable over United States Patent Application Publication number 2002/0009738 A1 (January 24, 2002) is maintained.

Applicants assert "the [patent publication] discloses the identification of tissue-specific polynucleotides and methods for determining the presence of cancer in a patient by detecting polynucleotides which encode breast tumor proteins." Applicants note the publication's polynucleotides do not necessarily encode expressed proteins and there are many polynucleotides, which are never translated. Applicants submitted a Declaration signed by Dr. Barry Dowell corroborating that assertion. Applicants continually assert how their claimed invention differs from the publication document in that the invention claimed "...relates to the detection of actual polypeptide markers (or complexes thereof) present in specific combinations.", see page 6 of the Remarks,

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second full paragraph. Applicants note the "...claimed invention is quite distinct from the teachings and suggestion of Houghton et al. [the patent application publication].", see page 7 of the Remarks submitted February 2, 2006. And in conclusion, Applicants state that MPA, BU101 and BS106 are not disclosed nor suggested in the patent application publication document, last paragraph of page 9 of the Remarks. These arguments, points of view and the declaration have been carefully considered but found unpersuasive.

Applicants' attention is directed to page 4, section 0056; page 5, section 0102; page 9, sections 0139 and 0145; page 12, section 0179; and page 8 of the Final Rejection mailed April 6, 2004. It is clear from the disclosure of US patent application publication #2002/0009738, Applicants' BS106 (SEQ ID NO: 8) and BU101 (SEQ ID NO: 6) are the same as the publication's sequence 31 and sequence 77, respectively are taught, see enclosed sequence alignment. It is also clear polynucleotides were translated and expressed as proteins/amino acid sequences, see page 4, sections 0055 and 0056; page 5, sections 0101 and 0102; and page 64, claim 8. These molecules are breast tumor proteins that may be detected in diagnostic methods, see abstract; page 9, section 0145; and page 66, claim 31.

The publication teaches that diagnosis of cancer can be performed and the change in the level of reactive polypeptide(s) evaluated, see page 9, section 0145. The publication also provides teachings of diagnostic methods, which include a monoclonal antibody or fragment thereof that specifically binds to a breast tumor protein, see page 12, section 0179. A variety of biological samples may be tested for

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the breast tumor proteins, such as urine, a tumor biopsy sample, or a lymph node, see page 9, section 0139. The publication provides the motivation that the detection of actual polypeptide markers (or complexes thereof) present in specific combinations may be conducted with a reasonable expectation of success, see page 1, section 0009; page 9, section 0145. It is clear from the prior art that an assay of a specific combination of breast tumor markers is contemplated and this detection includes the use of antibodies, see page 1, section 0009; page 9, section 0145; page 12, section 0179; and page 17, section 0209. The rejection is maintained for the established reasons addressed above and for the reasons of record.

### ***Conclusion***

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.


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5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571) 272-0831. The Examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

**ALANA M. HARRIS, PH.D.**  
**PRIMARY EXAMINER**

  
Alana M. Harris, Ph.D.  
16 June 2006